



Panelist Presentation

Localization of Pharmaceutical Production and the Dissemination of Health Technologies

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2021 trade and public health virtual course webinar:
dissemination of health technologies

YouTube link: <https://youtu.be/Sx4KottMKAY>

12 May 2021 - 14:00 to 16:30 (CET)

Background Studies

Opportunities, Constraints and Critical Supports for Achieving Sustainable Local Pharmaceutical Manufacturing in Africa: With a Focus on the Role of Finance

Final Report
18th March 2021

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A landscape mapping and analysis of financing for African manufacturing of COVID-19 diagnostics, vaccines, therapeutics and essential PPEs

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Nova Worldwide Consulting®

China policies to promote local production of pharmaceutical products and protect public health



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Indian policies to promote local production of pharmaceutical products and protect public health



Health and Industrial Policies

- World Health Organization (WHO) has promoted local production of medicines for several reasons
 - Improving security of supply
 - Building health technology infrastructure
 - Promoting science and technology
 - Enhancing regulatory capacity
 - Disincentivizing substandard drugs
 - Better addressing local patient needs
 - Reducing payment outflows for imports
- COVID 19 has illustrated risks of dependence on imports
 - Localization of production increasingly perceived as matter of “public health security”

Local Production “Ingredients”

- Large array of evolving technologies
- Diagnostics, therapeutics and vaccines
- Transitioning from small chemical to biologic based
- Financing
- Property, machinery and equipment (including software)
- Infrastructure and utilities
- Raw materials, intermediates, APIs, finishing components (e.g., excipients, packaging)
- Biologic materials
- Preponderance of global production is private sector
 - China “mixed” ownership affects equation – government holds stakes in major producers

Generic and Originator Markets

- Generic drug market intensely price-competitive
- Competitive advantages are held by countries with substantial domestic markets, supportive government policies (including direct and indirect subsidies), and well-developed internal infrastructure
 - China and India advantages
 - Followed somewhat different policy paths
 - Pre-TRIPS and/or weak IP environment facilitated build-up
 - India early penetration of high-income markets
 - Stringent GMP compliance role

Generic and Originator Markets

- Originator market competitive advantages derive from R&D expenditure and legislated "monopoly" positions
- Originator business models do not ordinarily encompass licensing patent/regulatory-protected distribution positions to independent third parties
 - Joint ventures and manufacturing outsourcing more common
- Manufacturing costs a comparatively minor part of originator pricing determinations
- Recovering R&D costs plus capital for future expenditure (which includes acquisitions)

Technology Necessary but Insufficient

- Recent study of African local production environment illuminates challenges
- Africa is diverse region of 54 countries with varying characteristics
 - Geographic, socio-economic, health burden, political system, infrastructure, education system, language and cultural tradition
 - Local production solutions should account for complexity
- Developing local pharmaceutical sector requires sound business models
 - Some national markets are of insufficient size to support robust manufacturing
 - International procurement funds limit purchases to stringent GMP-compliant products; few produced in Africa
 - Government procurement policies are directed toward lowest cost/price suppliers that are typically outside the continent

Technology Necessary but Insufficient

- Barriers to trade include tariffs and non-integrated regulatory approval processes
- Problem is not lack of global availability of investment capital, but demonstrating profit-potential to prospective investors
 - Global financial markets currently “awash” with capital seeking returns
- Vaccine market is distinct in that demand must almost certainly be sustained by government intervention
 - Market for "pandemic vaccines" is episodic making private investment challenging absent support
 - Advance purchase commitments, continuing subsidies, etc.

Solutions

- Improve market structure
 - Regional production hubs
 - Regional procurement mechanisms
 - Integration of regulatory approval processes
 - Regional integration of trade
- Bolster financial support
 - Development Bank backstops (credit guarantees)
 - Sovereign Wealth Fund investment
 - World Bank lending facilitation
 - IMF liquidity assistance to central banks to facilitate domestic lending and grants
 - Local production as “social impact” investing
 - Transparent foundation funding window

Solutions

- Government policy instruments
 - Prioritize development of local production (including infrastructure) as component of national (public health) security comparable to defense, energy grid and agriculture
 - Employ subsidies, tax incentives, procurement preferences, tariffs (particularly to offset foreign government intervention) as infant industry support
 - Higher income countries and regions employ these tools routinely
 - US \$30+ billion annual R&D subsidies through NIH and massive pandemic response subsidies
 - EU Airbus supports, China domestic technology incentives
 - Consider using flexibilities provided by WTO rules applicable to regional arrangements
 - Localized production may not mean lower pharmaceutical prices in near to medium term as initial costs absorbed
 - Net longer term benefits include employment, reduced payments outflows, science and technology infrastructure, other spillovers

Solutions

- Technology transfer mechanisms
 - Joint venture arrangements
 - Technical training institutes
 - WHO technology hub
 - Non-voluntary license option in reserve
- GMP upgrading for health benefits, to engage international procurement and to expand export opportunities
- Inherent in enhancing local production capacity is expansion of regional R&D efforts
- Recent trend to prohibit technology transfer as condition of direct investment (including joint ventures) in bilateral and regional trade agreements
 - Consider whether this is appropriate policy for developing economies seeking to enhance technology capacity